

REMARKS

Claims 1-30 are pending with claims 21-23 having previously been withdrawn based on a previous election requirement.

Initially, the indication of allowable subject matter in claims 4-6, 8, 9, 16-20, 27 & 30 is noted with appreciation.

Accordingly, claim 4 is rewritten in independent form to recite the limitations of its base claim 1 so that claim 4, and claims 5 and 6 which depend cognately therefrom, should now be in condition for allowance, and claim 8 is rewritten in independent form to recite the limitations of its base claim 1 so that claim 8, and claim 9 which depends therefrom, should now be in condition for allowance. Similarly, claim 16 is rewritten in independent form to recite the limitations of its base claim 10 so that claim 16, and claims 17-20 which depend cognately therefrom should now be in condition for allowance, and claim 30 is rewritten in independent form to recite the limitations of its base claim 10 so that claim 30 should now be in condition for allowance. In addition, previously withdrawn claims 21-23 all depend cognately from allowable claim 17, and thus it is believed proper to reinstate these withdrawn claims into the present application to be allowed therewith. Claim 27 is rewritten in independent form to recite the limitations of intervening claim 25 and base claim 24 so that claim 27 should now be in condition for allowance.

Where appropriate, the objections to claims 1-9 are all addressed by amendments herein.

Claim 10 is amended to address the indefiniteness rejection thereof.

Claim 1 is directed to a connecting assembly for interconnecting spinal rods secured to spinal vertebrae and calls for a pair of spinal rod connecting devices and a contact surface of each of the connecting devices for seating on one of the spinal rods. A locking member is recited for being shifted between a clamp position with the locking member clamping the spinal rod against the contact surface in an unclamped position with the spinal rod released. As amended, claim 1 calls for a non-threaded rotatable actuator operable to shift the locking members between the clamped and unclamped positions. The non-threaded actuator member is configured to be rotatable by a predetermined rotary amount less than one full turn thereof to a predetermined locked position thereof corresponding to the clamp position of the lock member on the spinal rod. Richelsoph et al. do not disclose or suggest the recited non-threaded rotatable actuator of amended claim 1.

In Richelsoph et al., set screws are provided, which must be threaded a number of revolutions into a corresponding hole until the surgeon *believes* that tight clamping has been achieved. This necessarily requires guess work on the part of the surgeon, based upon the "feel" of the set screw as torque is applied. Since there is no predetermined locked position for set screws, it is easy for a surgeon to fail to fully lock the assembly, or on the other hand, to overtorque the set screw, which can strip the threads of the screw or otherwise damage the assembly. The claimed unthreaded rotatable actuator has a number of advantages over set screws shown in prior art references. For instance, an unthreaded actuator that is locked with a predetermined amount of rotation cannot be cross-threaded and also provides a surgeon with certainty, since it is known that the device is locked when the actuator is rotated by the specified predetermined amount. The surgeon need not rely on his own experience or

skill to determine that locking has been achieved, because the predetermined locked position provides an objective indicator that the clamp device has been locked once the actuator has been rotated to a specified angle. The predetermined locked position also eliminates the need for a torque driver, since the actuator cannot be accidentally overtorqued to damage the assembly and/or spinal rod (see, *e.g.*, paragraphs 8 and 49 of this application's specification). The claim also now requires that the predetermined rotary amount is less than one full turn, to even more clearly distinguish the claimed actuator from set screws, which often must be rotated a number of times to effect a desired amount of linear shifting. Therefore, the claimed unthreaded actuator member configured to be rotated by a predetermined rotary amount less than one full turn to a predetermined locked position minimizes unwanted stress and physical damage to the rod, connecting device, and the actuator itself. Since at least this feature is absent in *Richelsoph*, claims 1-3 and 7 should be allowed.

Claim 10 is directed to a connecting assembly for interconnecting spinal rods secured to spinal vertebrae with the connecting assembly including a pair of spinal rod connecting devices for being connected to a respective pair of spinal rods, and a cross rod having opposite ends and a central longitudinal rod axis extending therebetween and being connected to a first one of the pair of spinal rod connecting devices at a first one of the opposite rod ends. Claim 10 further calls for a rod receiving member having a central longitudinal receiving axis and being connected to a second one of the pair of spinal rod connecting devices with the rod receiving member including an internal bore oriented along the receiving axis and being configured for adjustably receiving a second one of the opposite rod ends so that the

rod may be pivoted with respect to the receiving axis to provide the rod with variable angles relative thereto and so that the cross rod may be shifted axially along the rod axis to variable depths within the bore of the rod receiving member. A clamp device is recited for clamping against the cross rod received in the rod receiving member. As amended, claim 10 requires a sleeve that extends about the rod receiving member and is shifted therealong for clamping the clamp device against the cross rod to fix the cross rod at an adjusted angle and at an adjusted depth within the receiving member. Shluzas does not disclose or suggest the recited sleeve of amended claim 10. In Shluzas, a first connecting member 30 contains a large opening 40 to receive one end of a cross rod 42. A second connecting member 44 is integrally connected to the cross rod. A set screw 58 clamps the cross rod 42 within the opening 40 to prevent relative movement between the cross rod 42 and first connecting member 30. (See Shluzas at ¶¶ 14-15). The Examiner has identified a set screw 58 in *Shluzas* as a clamp device; however, there is no corresponding sleeve extending about the rod receiving member and shifted therealong to clamp the set screw (or any other “clamp device”) against the cross rod. Furthermore, if the ball 48 in *Shluzas* were considered a clamp device, there is still no sleeve to clamp the ball. As previously stated, the clamping in Shluzas is provided by the set screw 34, not a sleeve. For at least these reasons, claims 10-15 should be allowed as written.

Claim 24 is directed to a connecting assembly for interconnecting a pair of spinal rods secured to spinal vertebrae with the connecting assembly including a pair of spinal rod connecting devices, and a cross rod for being connected to one of the connecting devices. As amended, claim 24 requires that the cross rod have a solid construction without a slot formed therein. A rod receiving member is connected to

the other connecting device with the rod receiving member including an internal bore for receiving the solid cross rod. Amended claim 24 further calls for a clamp device configured for extending about and clamping against the solid cross rod when received in the rod receiving member. The sleeve is operable for clamping the clamp device against the solid cross rod, and side openings in the receiving member open to the bore to allow the solid cross rod to be pivoted in and out of the bore through the side openings. Lee et al. do not disclose or suggest the solid cross rod, as required in amended claim 24. In Lee, an adjustment screw penetrates through two flat bridge members and is tightened to fixedly couple the bridge members. This system is quite different than what is claimed. The claims require a solid cross rod that is received in an internal bore of a receiving member. A clamp device is also recited that extends about the solid cross rod in the assembly of claim 24. In Lee, a flat first bridge member having a slot therein is provided instead of a solid cross rod having no slot. The first bridge member is received between flat upper and lower extensions of a second bridge member rather than an internal bore. Additionally, Lee does not disclose a clamp device to extend about and clamp against a cross rod or any similar structure. Instead, Lee provides an adjustment screw that extends between the flat upper and lower extensions of the second bridge member and penetrates through the slot in the first bridge member. For these reasons, claims 24-26 should be allowed.

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CONCLUSION

For the foregoing reasons, it is respectfully requested that claims 1-30 be allowed to pass to issue.

The Commissioner is hereby authorized to charge any additional fees which may be required with respect to this communication or credit any overpayment to Deposit Account No. 06-1135.

Respectfully submitted,
FITCH, EVEN, TABIN & FLANNERY

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